IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 14-829 (SLR)(SRF)
	)	
ACTAVIS ELIZABETH LLC,	)	
	)	
Defendant.	)	

ACTAVIS' ANSWERING BRIEF ON CLAIM CONSTRUCTION

Of Counsel:

George C. Lombardi
Michael K. Nutter
Ivan M. Poullaos
Karl A. Leonard
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tel: (312) 558-5600
Fax: (312) 558-5700

PHILLIPS, GOLDMAN & SPENCE, P.A.
John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806-4204
Tel : (302) 655-4200
Fax : (302) 655-4210
jcp@pgslaw.com
dab@pgslaw.com

Attorneys for Actavis Elizabeth LLC.

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

INTRODUCTION

The disputed constructions in this case can be reduced to a singular question: whether the asserted claims encompass a "random mixture." They undoubtedly do not, but are instead drawn to a special type of mixture in which the particles are ***adhered*** to one another, as in an "ordered mixture." Accordingly, Actavis' constructions should be adopted. An "ordered mixture" (also known as an "interactive mixture") is characterized by certain *forces* that exist between smaller particles that stick to the surface of larger "carrier particles." By contrast, in a "random" or a "simple" mixture, there are no such interactive forces—the particles are simply mixed, and no particle "carries" anything else.

Although Orexo pays lip service to the specifications and prosecution histories, its proposed constructions ignore both in a thinly-veiled attempt to expand the patents to read on random mixtures. Orexo contradicts and undercuts the alleged novelty of these patents, and the very reason they were granted in the first place—the fact that the patents are directed to the sublingual administration of an "ordered mixture" tablet. Orexo ignores specific admissions in the specification of U.S. Patent No. 8,454,996 ("the '996 patent"), and downplays the unmistakable import of the examiner's amendment to U.S. Patent No. 8,940,330 ("the '330 patent"). And of course, Orexo also ignores that a person of ordinary skill in the art ("POSA") would have understood that the placement of one particle at the surface of a "carrier particle"—a term-of-art—encompasses an ordered mixture, not a random one. In the face of two decades of literature that Orexo simply ignores and fails to bring to the Court's attention, Orexo attempts to read this term-of-art to simply mean "particle" and to include no interactive forces at all.

The evidence is unambiguous that neither asserted patent covers a random mixture. The specification of the '996 patent—the earlier of the two asserted patents—admits that regular

"sublingual formulations" were "presently available" at the priority date.[1] (JA04, '996 patent, col. 1, line 45.) Thus, the mere sublingual administration of a random mixture tablet would not justify patent protection. That is why the '996 patent specification makes clear that the invention "comprises an . . . ordered mixture . . . ." (JA01, '996 patent at Abstract.) Similarly, during prosecution of the '330 patent, the examiner ***added an express requirement*** that the broadest claim exclude random mixtures when he amended it to require that the smaller particles be presented upon the surface of "carrier particles."

Orexo's attempt to read the asserted patents onto random mixtures is flatly inconsistent with the intrinsic record, not to mention the way a POSA would have understood the concept of "carrier particles." Moreover, a POSA would never lose sight of the alleged basis of patentability—the sublingual administration of an ordered mixture. This Court should construe the claims to be limited to such a mixture (thus excluding random mixtures), and should therefore adopt Actavis' proposed constructions that make clear there are ***interactive forces of adhesion*** associated with the carrier particles.

BACKGROUND

I. Ordered mixtures are a special kind of mixture—distinct from random mixtures.

A. The '996 specification explains the concept of an ordered mixture.

The '996 specification defines ordered mixtures by reference to European patent EP 0324 725. (JA05, '996 patent, col. 3, lines 39-42.) That European application states that in an ordered mixture, "the smaller particles ***adhere or bind*** to the surfaces of the larger ***carrier particles***." (JA3268, EP '725 reference, col. 1, lines 16-22 (emphasis added).) In this vein, the '996

[1] Unless otherwise specified, Actavis will use "the time of the application" or "the priority date" to refer to the earliest possible priority date of the '996 patent, the earlier of the two asserted patents: September 24, 1998. Actavis reserves the right to challenge this priority date at the appropriate time.

specification repeatedly highlights the attachment between the smaller particles and the carrier particles:

- "The composition comprises an essentially water-free, ordered mixture of at least one pharmaceutically active agent in the form of microparticles which are adhered to the surfaces of carrier particles . . ." (JA01, '996 patent, Abstract (emphasis added).)
- " . . . the sublingual composition comprises an ordered mixture of one or more bioadhesive and/or mucoadhesive carrier substances coated with the pharmaceutically active agent or agents in a fine particulate form." (JA05, '996 patent, col. 3 lines 34-38.)
- "The invention is particularly suitable for the administration of fentanyl . . . Fentanyl is caused to adhere to the ***carrier particles*** by dry mixing of the ingredients during a period of time of sufficient length." (JA07, '996 patent, col. 7, lines 7-15 (emphasis added).)

B. The '330 specification also explains the concept of an ordered mixture.

The '330 patent similarly explains that in an ordered mixture, smaller particles are affixed to the larger carrier particles. The specification states that an ordered mixture (also called an "interactive mixture") "denote[s] a mixture in which particles do not appear as single units, as in random mixtures, but rather where smaller particles . . . are attached to (i.e. adhered to or associated with) the surfaces of larger carrier particles." (JA25, '330 patent, col. 7 lines 5-19.) These mixtures are "characterized by interactive forces" between the carrier particle and the smaller particles attached to it, such as: (1) van der Waals forces; (2) electrostatic or Coulomb forces; and (3) hydrogen bonding. *Id.*

According to the patentees, the use of an ordered mixture in the claimed invention produces "increased bioavailability" compared to the random mixtures of the prior art.[2] (JA28, '330 patent, col. 14, lines 61-65.)

[2] Actavis reserves the right to challenge this assertion at the appropriate time.

C. Well before the priority date, a POSA would have been familiar with the concept of an ordered mixture.

1. In an ordered mixture, smaller particles are affixed to the surface of larger carrier particles.

Since the 1970s, POSAs have understood that in an ordered mixture, smaller particles are affixed or adhered to the surface of larger carrier particles, just as the patents in this case describe. (Berner Decl. at ¶¶ 22-31.) As a seminal 1975 article put it, "[o]rdered mixing may be considered to be different from random mixing since it . . . requires particle interaction, i.e. adsorption, chemisorption, surface tension, frictional, electrostatic or any other form of ***adhesion***." (JA3277, J.A. Hersey, *Ordered Mixing: A New Concept in Powder Mixing Practice*, POWDER TECH., 11: 41-44 (1975) ("Hersey 1975") at 41 (emphasis added); (Berner Decl. at ¶ 24).) Another article, from 1981, similarly highlighted the central role of the interactive forces between the particles:

> The fundamental difference which distinguishes an ordered mix from a random mix is the nature of the forces which constrain the different sets of particles to remain in the position they achieved during the mixing process. Particles in a random mix . . . are mainly influenced by the force of gravity. In fact in a truly random mix there will be no cohesive or adhesive forces between the different particles. In an ordered mix . . . the particles are also influenced by the force of gravity. However, this only applies to the ordered units. Within an ordered unit, ***the fine particles are bound to the coarse ones by interparticulate forces*** which result from surface electrical attractions.

(JA3284, J.N. Staniforth, *Total Mixing*, INT'L J. PHARM. TECH. & PROD. MFR., 2(1): 7-12 (1981) ("Staniforth 1981") at 8 (emphasis added).) Other references reinforce this fundamental concept of ordered or interactive mixtures:

- "Fine particles adhere to other particles to form so-called ordered units." (JA3289, J.N. Staniforth, *Ordered Mixing or Spontaneous Granulation?* POWDER TECH., 45: 73-77 (1985) ("Staniforth 1985") at 73.)

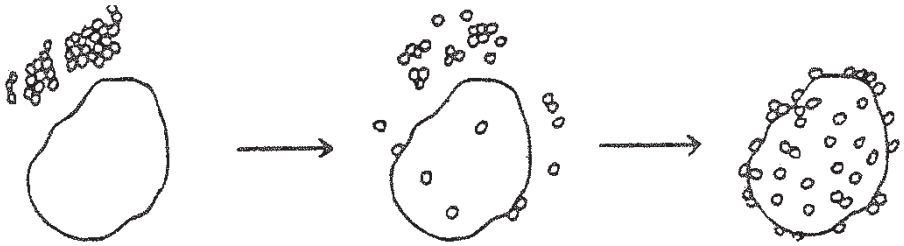
- "Adhesion between fine and coarse components must be accomplished. The fine component must have sufficient intrinsic cohesiveness to adhere to the surface of the more coarse component." (JA3307, Marie Westerberg, *Studies on Ordered Mixtures for Fast Release and Dissolution of Drugs with Low Aqueous Solubility*, Doctoral thesis at Uppsala University 1992 from the Department of Pharmaceutics ("Westerberg 1992") at 13.)

In fact, so important is the concept of adhesion that Westerberg notes several prior art researchers who suggest that the term "interactive mixture" or "***adhesive*** mixture" be used as a more "relevant" descriptor than the term "ordered mixture." (*Id.*) Nevertheless, Westerberg uses the term "ordered mixture" as the term-of-art. (*Id.*) The inventors of the '996 patent were no strangers to these teachings. One of them, Christer Nystrom, was Westerberg's thesis advisor. (JA3332, Westerberg 1992 at 38.)

Unlike an ordered mixture, in a random mixture there is no adhesion between the particles. (*E.g.*, JA3277, Hersey 1975 at 41 (emphasis added); (Berner Decl. at ¶ 22).)

2. Ordered mixtures are created by deagglomerating the smaller particles so they can adhere to the carrier particle.

The first step in creating an ordered mixture is to break the forces between the smaller particles that tend to agglomerate together. (JA3306, Westerberg 1992 at 12.) Second, "[a]dhesion between fine [microparticles] and coarse [carrier particles] components must be accomplished." (JA3307, Westerberg 1992 at 13.) In other words, "[t]he fine component [microparticle] must have sufficient intrinsic cohesiveness to adhere to the surface of the more coarse component [carrier particle]." (*Id.*) Westerberg used the below diagram to describe an ordered mixture: "[d]ry coating of coarse carrier particles by a small amount of fine particles."



(JA3305, Westerberg 1992, at 11.)

3. The placement of one particle at the surface of a "carrier particle" suggests that a mixture is an ordered mixture.

A POSA would have understood a "carrier particle" with other particles on its *surface* is not a random mixture; rather, it signifies the presence of what is often called an ordered mixture. (Berner Decl. at ¶¶ 32-36.) In a random mixture, the particles are simply mixed together; nothing "carries" anything else and there are no interactive forces involved. (*Id.*) Accordingly, those in the art, including one of the listed inventors of the '996 patent (Nystrom), have consistently used the term "carrier particle" to discuss an ordered mixture:

- "In an ordered powder mix (Hersey 1975), fine drug particles are distributed fairly evenly on coarse carrier particles." (JA3342, Christer Nystrom and Marie Westerberg, *The use of ordered mixtures for improving the dissolution rate of low solubility compounds*, J. PHARM. PHARMACOL. 38: 161-165 (1986) ("Nystrom/Westerberg 1986") at 162.)

- "It was believed that in the ordered mixture, individual drug particles were *adhering* to the *carrier particles* . . ." (JA3348, M. Westerberg, B. Jonsson, and C. Nystrom, *Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures*, INT'L J. OF PHARMACEUTICS, 28: 23-31 (1986) ("Westerberg/Jonsson/Nystrom 1986") at 23 (emphasis added).)

- "Irregular particles *adhere* to indentations on the surface of the *carrier particles* and form stable ordered mixtures." (JA3359, L.W. Wong and N. Pilpel, *The effect of the shape of fine particles on the formation of ordered mixtures*, J. PHARM. PHARMACOL. 40: 567-568 (1988) ("Wong 1988") at 567 (emphasis added).)

A POSA would have understood that "carrier particle," a term-of-art, had one other possible meaning: a particle that carries other particles embedded within it. (Berner Decl. at ¶ 32.) But it is undisputed that that is not what the patents require. Rather, the patents require that microparticles be at the *surface* of the carriers—i.e., not a random mixture, but one involving forces of *adhesion* as in an *ordered* mixture.

II. Sublingual administration of random mixtures was known in the prior art.

The '996 patent specification admits that "sublingual formulations" were "presently available" at the time of the patent application. (JA04, '996 patent, col. 1, line 45.) The Patent Office agreed, recognizing that tablets were "well known for sublingual administration." (JA2001, 12/20/12 Office Action at 7).

For instance, the prior art U.S. Patent No. 4,935,428 ("the '428 patent") (issued in 1990) disclosed a "pharmaceutical composition in sublingual unit dosage form for maintenance treatment of opiate addicts." (JA3361, '428 patent at Abstract.) This composition was prepared by simple mixing. For instance, the sublingual tablets in Example 2 of the '428 patent were prepared by screening various ingredients and simply "blending them together." (JA3363, '428 patent, col. 4, lines 41-64.) After additional processing steps, such as aqueous granulation, the resulting granules were blended further and compressed into tablets. (*Id.*; *see also* Berner Decl. ¶¶ 37-40.)

Thus, given the state of the art, anyone wishing to obtain a patent for a sublingual formulation had to distinguish the alleged invention from these well-known prior art random mixtures.

III. The '996 patent claims sublingual administration of an ordered mixture tablet.

In an effort to surmount the prior art, the '996 patent is directed to a sublingual formulation of an ***ordered*** mixture. (Berner Decl. ¶¶ 48-59.) The specification could hardly be clearer about this, as these excerpts show:

> "The composition comprises an essentially water-free, ordered mixture of at least one pharmaceutically active agent in the form of microparticles which are adhered to the surfaces of carrier particles . . ." (JA01, '996 patent, Abstract (emphasis added).)
>
> "According to the invention, the peroral treatment of acute disorders comprises sublingual administration of an ***ordered mixture*** comprising a pharmacologically effective amount of at least one pharmaceutically active agent." (JA04, '996 patent, col. 2 lines 64-67 (emphasis added).)
>
> "Still further according to the invention, the sublingual composition comprises an ordered mixture of one or more . . . carrier substances coated with the pharmaceutically active agent . . ." (JA05, '996 patent, col. 3, lines 34-38.)
>
> "In such an ordered mixture, the active agent or agents have a mean particle size below 10 μm." (*Id.* at col. 3, lines 62-63.)
>
> "The ordered mixtures prepared in accordance with the present invention can be incorporated into various kinds of pharmaceutical preparations intended for sublingual administration." (JA07, '996 patent, col. 7, lines 36-39.)
>
> "A pharmaceutical composition for the preferred sublingual route of administration can be obtained by combining an aforementioned ordered mixture with conventional pharmaceutical additives and excipients used in the art for sublingual preparations." (*Id.* at col. 7, lines 47-51.)

The specification also emphasizes the purported novelty of an ordered mixture for sublingual administration. Although "sublingual formulations" were "[p]resently available" (JA04, '996 patent, col. 1, lines 45-47), the specification explains that the "prior art technique of using an ordered mixture for rapid drug dissolution has hitherto only been reported to be suitable for conventional oral drug therapy." (JA05, '996 patent, col. 3, lines 47-49.) By contrast, according to the patent:

> [t]he possibility to use ordered mixtures for sublingual administration, where the volume of liquid available as a solvent is limited to a few millilitres, has not been considered as a feasible approach. It was therefore unexpected that the present form of a solid dosage form preparation and administration route gives positive and useful results.

(*Id.* at col. 3 lines 56-61.) Without conceding the accuracy of those latter statements (and Actavis vigorously disputes them), the point for claim construction purposes is that the patent very clearly stakes out the use of an ordered mixture as being the key feature that was purportedly inventive and which conferred desired benefits. And an ordered mixture involves forces of adhesion to the carrier particle.

The claims of the ’996 patent use a term-of-art, “carrier particles,” to claim the ordered mixture that was so clearly delineated in the specification. (Berner Decl. at ¶¶ 43, 48.) Specifically, claim 1 is directed to a sublingual tablet with microparticles and carrier particles, “wherein the microparticles . . . are presented at the exterior surfaces of the carrier particles.” (JA09, ’996 patent, claim 1.) In addition to the basic ordered mixture, claim 2 requires that the composition be “essentially water free” and not necessarily limited to a “tablet.” (*Id.* at claim 2.)

IV. The ’330 patent claims were rewritten by the examiner to exclude random mixtures, and instead require an ordered mixture.

The ’330 patent adds additional limitations that go beyond the ’996 patent, but it too claims a mixture involving forces of adhesion, as in an ordered mixture. As with the ’996 patent, a POSA would have easily understood as much by reading the claim language and the intrinsic record. (Berner Decl. at ¶¶ 62-74.)

The ’330 specification was written before the claims were amended to read as they do today. In fact, the specification is written permissively and purports to encompass ***random mixture*** sublingual tablets in the scope of the invention. In the language of the Abstract, the invention is described as a composition comprising “microparticles . . . in associative admixture

with" other particles. (JA10, '330 patent, Abstract.) As the specification goes on to explain, "associative admixture" means that "some form of mixing step . . . render[s] [the particles] in intimate contact with each other," ***preferably*** "in the form of a[n] interactive mixture comprising at least one population of carrier particles upon the surfaces of which are presented (e.g. adhered) microparticles . . . ." (JA24-25, '330 patent, col. 6, line 48-col. 7, line 4.)

Initially, given the permissive language of the specification, the patentees sought broad claims encompassing a tablet made from a simple mixture of ingredients. Even after preliminary amendment, the primary independent claim (then claim 24) did ***not*** refer to "carrier particles," but rather read:

> A tablet suitable for sublingual administration comprising:
>
> Microparticles of a pharmacologically-effective amount of buprenorphine, or a pharmaceutically-acceptable salt thereof in contact with particles comprising citric acid;
>
> A pharmacologically-effective amount of naloxone, or a pharmaceutically-acceptable salt thereof; and
>
> A disintegrant selected from the group crosscarmellose sodium, sodium starch glycolate, crosslinked polyvinylpyrrolidone and mixtures thereof.

(JA2981, 9/18/14 Amendment.) With no reference to "carrier particles," this claim was initially directed to a tablet made from ***any*** mixture, including a random mixture. Indeed, proposed dependent claim 26 purported to add the limitation—solely for claim 26—that the composition be "presented as an ***interactive mixture*** comprising microparticles of buprenorphine or a pharmaceutically acceptable salt thereof presented upon the surfaces of ***carrier particles***." *Id.* (emphasis added). In other words, the independent claim was not initially limited to an "interactive mixture comprising microparticles . . . presented upon the surfaces of carrier particles."

The breadth of these claims presented a problem. As the '330 specification admits, the prior art to this patent includes a buprenorphine-containing sublingual tablet called Suboxone®, which is "formed by compression of a random mixture." (JA28, '330 patent, col. 13, lines 9-23.) As would be expected, especially given that the priority date of the '330 patent is well after that of the '996 patent, the examiner rejected the broad claims and only allowed ones that did ***not*** read on a random mixture, but rather on an ordered mixture. Specifically, the examiner's amendment cancelled claim 26 (JA3020, 11/4/14 Notice of Allowability), and moved the "carrier particle" limitation into the main independent claim (which became claim 1 of the '330 patent), so that it read as follows:

> A tablet composition suitable for sublingual administration comprising:
>
> microparticles of a pharmacologically-effective amount of buprenorphine, or a pharmaceutically-acceptable salt thereof, ***presented upon the surface of carrier particles***, wherein microparticles of buprenorphine or a pharmaceutically-acceptable salt thereof are in contact with particles comprising citric acid, wherein the buprenorphine or pharmaceutically acceptable salt thereof and the citric acid are not in the same particle;
>
> a pharmacologically-effective amount of naloxone, or a pharmaceutically-acceptable salt thereof; and
>
> a distintegrant selected from the group consisting of croscarmellose sodium, sodium starch glycolate, crosslinked polyvinylpyrrolidone and mixtures thereof.

(JA3019-20 (emphasis added).)

Thus, in the end, as with the '996 patent, the '330 patent issued with claims that did not cover a random mixture. Rather, they require intermolecular forces of adhesion, as in an ***ordered*** mixture.

LEGAL STANDARD

"The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). "[T]he specification is always highly relevant to the claim construction analysis." *Id.* at 1315 (internal quotation marks and citation omitted). The "prosecution history can often inform the meaning of the claim language by demonstrating . . . whether the inventor ***limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be***." *Id.* at 1317 (emphasis added). Finally, the court may "look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharms. USA v. Sandoz*, 135 S. Ct. 831, 841 (2015). But the ultimate inquiry remains: "whether a skilled artisan would ascribe that same meaning to that term in the context of the specific patent claim under review." *Id.* (emphasis removed).

Importantly, the "intrinsic evidence" includes "prior art cited in a patent." *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364, 1368 (Fed. Cir. 2003). "'When prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons of skill in the art, but also that the patentee intended to adopt that meaning.'" *Id.* (quoting *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1045 (Fed. Cir. 2000)); *see also Chimie v. PPG Indus.*, 402 F.3d 1371, 1380 (Fed. Cir. 2005) (affirming reliance on patent disclosure where patentee "chose to define [claim] term . . . solely by reference to the characteristics of the prior art").

ARGUMENT

Actavis' claim constructions are consistent with the intrinsic evidence, the extrinsic evidence, and the understanding of a POSA, as explained by Dr. Bret Berner. Dr. Berner has over 35 years' experience in the pharmaceutical industry, including with Proctor & Gamble, Ciba-Geigy, and Depomed, during which time he has developed and formulated a wide array of pharmaceuticals, including for sublingual delivery. (Berner Decl. at ¶¶ 4-9, and at Ex. A (curriculum vitae).) Dr. Berner is also a named inventor on over fifty U.S. patents. In addition, Actavis' proposed constructions are consistent with the constructions of a related patent by the District Court for the District of New Jersey in *Orexo v. Mylan*, C.A. No. 11-3788, 2014 WL 1302056 (D.N.J. Mar. 31, 2014), the very case that Orexo relies on in its brief. The Court should therefore adopt Actavis' proposals as explained further below.

I. A POSA would have understood the disputed terms to mean that the claims read on an ordered mixture.

Cut to its core, the disputed terms can be resolved once it is recognized that the claimed inventions do not cover random mixtures, but rather are directed to an "ordered" or "interactive" mixture. The patent specifications say that they are, and the file history confirms that that is exactly what the inventors and patent examiner understood the claimed inventions to be.

A. A POSA would have understood the claim term "carrier particles" as used in the patent to indicate adhesion with particles on the surface, as in an ordered mixture.

Term: Carrier Particles

Orexo's Proposed Construction	Actavis' Proposed Construction
In the context of the claims, particles comprising one or more pharmaceutically acceptable substances, at or near the surfaces of which may be other particles.	pre-formed particles comprising one or more pharmaceutically acceptable substances, attached to the surfaces of which are other particles

A POSA would have understood that the claims' reference to "carrier particles" encompasses an ordered mixture.[3] (Berner Decl. at ¶¶ 41-74.) After all, in a random mixture, nothing "carries" anything else; the particles are simply mixed together. (*Id.* at ¶ 22.) By contrast, POSAs have known since at least 1981 that "[t]he fundamental difference which distinguishes an ordered mix from a random mix is the nature of the forces which constrain the different sets of particles to remain in the position they achieved during the mixing process. . . . . In an ordered mix . . . the fine particles are ***bound*** to the coarse ones by ***interparticulate forces*** which result from surface electrical attractions." (JA3284, Staniforth 1981 at 8 (emphasis added).) As explained above (at 9-11), the patent examiner shared the same view, inserting an express requirement that the claims of the '330 patent contain microparticles on the surface of "carrier particles" in order to distinguish them from the prior art random mixtures.

But Orexo's proposed construction takes a different tack, and only requires that the other particles are "at or near the surfaces" of the carrier particle. According to Orexo and its expert, "any properties of the carrier particles are addressed by express language in the claims, and not by the phrase 'carrier particles' itself." (D.I. 73, Peppas Decl. ¶ 33-34, 70-71, 79.) But under that interpretation, a "carrier particle" becomes simply a "particle," as in a ***random*** mixture. (Berner Decl. ¶¶ 42-43.) Such a construction, which robs the term of its most basic meaning, cannot be correct—especially because the term was critical to the issuance of the patents. The specifications, the prosecution histories, and the claim language all point to the same conclusion.

[3] During the meet-and-confer process, Actavis did not hesitate to change its proposed constructions (or to agree to split up phrases into separate limitations) in an effort to narrow the issues and construe the terms that Orexo thought were in need of construction. Throughout its brief, Orexo seeks to draw attention to these changes in an effort to cast aspersions on Actavis for doing so. But Actavis' flexibility and willingness to respond to Orexo's proposals underlines the very point of a meet-and-confer process, and indicates Actavis' good faith participation.

1. The specifications make clear that the term "carrier particles," as used in the patent, denotes the adhesion of an ordered mixture.

As described above, the '996 patent unambiguously states that "[a]ccording to the invention, the peroral treatment of acute disorders comprises sublingual administration of an ordered mixture comprising a pharmacologically effective amount of at least one pharmaceutically active agent" (JA04, '996 patent, col. 2 lines 64-67), and repeats this theme throughout the specification. (*See supra* at 8.) The patentees admit that "sublingual formulations" were "[p]resently available" at the time of the application. (JA04, '996 patent, col. 1, line 45.) Thus, if this alleged invention is patentable at all, it would be because it claims the sublingual administration of an ***ordered*** mixture. According to the specification, this had "not been considered as a feasible approach." (JA05, '996 patent, col. 3 lines 56-59.)

The specifications also demonstrate that in an "ordered mixture," the smaller particles are affixed or adhered to the surface of the carrier particles. For instance, the '330 patent explains that in an ordered mixture, "particles do not appear as single units, as in random mixtures, but rather where smaller particles . . . are attached to (i.e. adhered to or associated with) the surfaces of larger carrier particles." (JA25, '330 patent, col. 7 lines 5-19.) This is a result of "interactive forces" between the particles, such as van der Waals forces, electrostatic or Coulomb forces, or hydrogen bonding. *Id.* The '996 patent, for its part, incorporates the EP '725 patent's teaching that in an ordered mixture, "the smaller particles ***adhere or bind*** to the surfaces of the larger carrier particles." (JA3268, EP '725 reference, col. 1, lines 16-22 (emphasis added).) The EP '725 patent has "particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons of skill in the art, but also that the patentee intended to adopt that meaning.'" *Kumar*, 351 F.3d at 1368. The specification also teaches that

in "an ordered mixture," "the finer particles exist as discrete primary particles adhered to the surfaces of the carrier particles." (JA06, '996 patent, col. 5 lines 62-67.)

Once again, Orexo submits that because the patents describe other properties of the carrier particles, such as identity, amount and size, the term "carrier particles" itself has no intrinsic meaning. (D.I. 72, Orexo's Op. Br. at 5-6, 15-16.) But once again, the mere use of a modifier such as "comprising any substance" does not rob a term such as "carrier particle" of its intrinsic meaning.

Orexo also points to the specifications' use of various terms to describe the relationship between the carrier particles and other particles: "coated," "positioned at," "adhered to," and "presented upon." (*Id.*) Orexo argues that these "alternatives" demonstrate that the claims do not require an ordered mixture. But this argument is circular. Nowhere does Orexo acknowledge a far more sensible possibility: the patentees used these terms interchangeably, and simply to describe ***what it is*** that is attached to the surface of the carrier particle. Indeed, the '330 specification supports that logical conclusion, and Orexo's admissions buttress it. To begin with, Orexo admits that "positioned" and "presented" mean the same thing. (D.I. 72, Orexo's Op. Br. at 9.) And the '330 specification states that in an interactive or ordered mixture, "smaller particles . . . are ***attached to (i.e. adhered to or associated with)*** the surfaces of larger carrier particles." (JA25, '330 patent, col. 7, lines 8-11.) Thus, although "associated with" and similar terms may seem more open-ended than "adhered," the specification itself shows that the terms are interchangeable. The specification also says "presented (e.g. adhered)" (*Id.*, col. 7, lines 1-4), again evidencing that they are not inconsistent terms. The most Orexo can say is that this creates an ambiguity—but that is an ambiguity that is resolved by the rest of the specification, the claim

language, and the prosecution history, all of which make clear that if the claims are novel at all, it is only because they claim a mixture involving ***adhesion***—just like an ordered mixture.

2. The prosecution histories show that "carrier particles," as used in the patent, denotes the adhesion of an ordered mixture.

As explained above (at 9-11), the patentee initially sought to obtain broad claims in the '330 patent that covered random mixtures. (JA2981.) But the examiner rewrote the claims (without re-writing the specification), and inserted an express limitation that the microparticles be "presented upon the surface of carrier particles." (JA3019-20.) The examiner did so by cancelling a dependent claim with this same limitation, thereby drastically narrowing the independent claim. (*Id.*) Simply put: these amendments show that the claims do ***not*** cover random mixtures, despite any broad language in the specification. But under Orexo's construction, the examiner amendments mean nothing.

Orexo makes only the most cursory of attempts to spin this history to its advantage, asserting (without explanation) that because the examiner concluded that Orexo's formulation demonstrated unexpected results, "carrier particles" should be construed as urged by Orexo. (D.I. 72, Orexo's Op. Br. at 19-20.) But that premise has nothing to do with the conclusion. To the contrary, the examiner's conclusion demonstrates that presenting microparticles on the surface of "carrier particles" was critical to patentability. Consequently, Orexo should not now be permitted to use claim construction to rewrite the claims to cover random mixtures when the Patent Office already determined that such claims were not patentable.

As for the '996 patent, nothing in the prosecution history teaches away from the clear language of the specification described above, not to mention the well-understood meaning of "carrier particles" itself. The '996 patent was allegedly inventive because it claimed a sublingual

formulation of an ***ordered*** mixture. In effort to read the claims onto random mixtures, Orexo makes two arguments, but each fails.

First, Orexo points to an amendment: because claim 1 was amended to substitute "presented at" for "adhered to," Orexo argues that the terms must have different meanings.[4] But as Orexo concedes, both claims refer to the surface of the "carrier particles." (D.I. 72, Orexo's Op. Br. at 6.) That use of "carrier particles" in the context of the patent signifies that neither claim covers a random mixture, and that both claims require an ordered mixture. Just as in the specification, the patentees use "presented" and "adhered" interchangeably. Moreover, as Orexo itself argues, these terms refer to the ***location*** of the smaller particles in the mixture—not necessarily the characteristics of the carrier particles themselves or the interactive forces between the carrier particles and the attached microparticles. (D.I. 72, Orexo's Op. Br. at 10, 19.)

Second, Orexo points to the examiner's comments about certain claims in other, related patents. For instance, in the examiner's view, certain such claims were "drawn to a product comprising components, not a method mixing components to form a product." (JA722-23.) Some of these arguments are highly misleading; for instance, in construing the '910 patent, the New Jersey court considered whether the patentee "disavowed methods of manufacturing that utilize water." (JA3192; *see* D.I. 72, Orexo's Op. Br. at 8.) That is a completely different issue than whether the composition is a random mixture, or an ordered mixture. In any event, Actavis agrees that the asserted claims are product claims. However, a POSA would have understood

[4] In a further effort to make this argument, Orexo makes a very brief reference to the *Mylan* court's construction of the '747 patent (not at issue in this case). (D.I. 72, Orexo's Op. Br. at 9.) Orexo argues that the court construed "presented" to mean "positioned." But the claims in that patent, like those here, went on to recite that the particles are on the "surfaces of the carrier particles." (JA3179.) The court did not imply that the verb "presented" changed the meaning of the critical term, "carrier particles." In fact, no claim construction opinion has even been issued on the '747 patent, so we have little indication of the court's reasoning.

that the term "carrier particles," as used in the claims, indicates that the product is characterized by intermolecular adhesion, as in an ordered mixture. (Berner Decl. at ¶¶ 32-36, 41, 48, 62.) A "mixture" is a product, not a process. The *Cambridge American English Dictionary* (2000) defines mixture as a product:

> a combination of substances resulting from mixing them together so that they cannot be easily separated

(JA3367.) The dictionary gives an example of the use of the word "mixture" to refer to a product: "It's a highly explosive mixture and has to be handled carefully." (*Id.*) The specifications use the term "ordered mixture" the same way. As one example, the '996 patent explains that "the sublingual composition comprises ***an*** ordered mixture" which is "coated with the pharmaceutically active agent or agents in a fine particulate form." (JA05, '996 patent, col. 3 lines 34-38 (emphasis added).) Of course, a "composition" cannot "comprise[]" a process.

3. The claim language makes clear to a POSA that the patents are directed to the adhesion of an ordered mixture.

The claims do not require the presence of microparticles presented/adhered on the surface of "particles"; they require microparticles to be presented/adhered on the surface of "***carrier*** particles." And as explained above (at 2-7), a POSA would understand that "carrier particles" ***carrying*** other particles at their surface is a key feature of ordered mixtures—***not*** random ones. (Berner Decl. ¶¶ 22-36.) The literature repeatedly refers to "carrier particles" when discussing ordered mixtures. To repeat just one example here, a 1986 article co-authored by Christer Nystrom—a named inventor of the '996 patent—consistently stresses that "carrier particles" are a component of ordered mixtures:

- The article is titled "Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures." (JA3348, Westerberg/Jonsson/Nystrom 1986, at 23.)

- "Six different carrier materials . . . were used to prepare ordered mixtures of micronized griseofulvin." (*Id.* at Abstract.)
- "Highly soluble carrier materials gave an extremely fast dissolution, probably due to the fact that the drug was delivered as free, well-dispersed primary particles, after rapid dissolution of the carrier particles." (*Id.*)
- "It was believed that in the ordered mixture, individual drug particles were adhering to the carrier particles . . ." (*Id.*)

Even Orexo has used the term "carrier particles" to denote an ordered mixture. In the New Jersey *Mylan* litigation, Orexo had to propose a construction for the claim term "ordered mixture." Orexo proposed the following: "[t]he particles of at least one material distributed fairly evenly ***on carrier particles***." (JA3186. (emphasis added)) In that case, the parties' dispute over that term had nothing to do with whether a carrier particle is an essential feature of an ordered mixture, and the *Mylan* court recognized that "there is no dispute that the carrier particles are also a part of the [ordered] mixture." (JA3204.) That should be beyond dispute here, too.

Unlike an ordered mixture, a random mixture will feature "no cohesive or adhesive forces between the different particles." (JA3284, Staniforth 1981 at 8.) In other words, ***no particle carries anything at its surface***, because the particles simply segregate or fall apart. (Berner Decl. ¶¶ 33, 68.) A POSA would have known all of this well before 1998, and would have understood that the term "carrier particle" with other particles at its surface, in the context of the claims, excludes a random mixture. Rather, it conveys the existence of adhesion forces as in an ordered mixture. In these special mixtures, intermolecular forces bind the microparticles to the carrier particles. (Berner Decl. at ¶¶ 22-31; *supra* at 2-5.) In fact, as Westerberg points out, several prior art researchers suggest that the term "interactive mixture" or "***adhesive*** mixture" should be used as a more "relevant" descriptor than the term "ordered mixture." (JA3305,

Westerberg 1992 at 11.) That is because in an ordered mixture, "[a]dhesion between fine and coarse components must be accomplished." (*Id.*; Berner Decl. at ¶¶ 22-31.)

With this in mind, Orexo's construction is erroneous because it would read the word "carrier" out of the claims, and rob the term "carrier particles" of all meaning. Orexo proposes that "the relationship between carrier particles and other materials is described by other words in the claim and not by the phrase 'carrier particles' itself." (D.I. 72, Orexo's Op. Br. at 16-17.) But the fact that other claim terms further describe the "carrier particles" does not rob the term of its intrinsic meaning: a particle that "carries" something else (here, microparticles). The *Mylan* court applied this principle when recognizing that the accompanying language of the claim actually helps to define the term. *Bd. of Regents v. BenQ Am. Corp.*, 533 F.3d 1362, 1368 n.5 (Fed. Cir. 2008) ("Other claim[] [language] . . . can also be valuable sources of enlightenment as to the meaning of a claim term.") (quoting *Phillips*, 415 F .3d at 1314). Here, the remaining claim language shows that the other particles are "carried" at the ***surface*** of the carrier particle, as in an ordered mixture. (Berner Decl. at ¶¶ 32-36, 41-43.)

With respect to the '996 patent only, Orexo makes a claim differentiation argument that simply misses the mark. In short, Orexo contends that claim 1 requires the buprenorphine be "presented at the exterior surfaces of the carrier particles," while claim 2 requires the buprenorphine be "adhered to the surfaces of carrier particles." So, according to Orexo, claim 1 cannot require that the buprenorphine be "adhered to" the carrier particles, as in an ordered mixture. Orexo is incorrect. Both claims require that the "carried" particles be at "the surface of carrier particles," and that is what conveys the properties of an ordered mixture, not a random one. It does not matter whether the patentee used the term "presented" or "adhered." In this context they both mean the same thing. It has long been clear that "two claims which read

differently can cover the same subject matter." *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.3d 1017, 1023 (Fed. Cir. 1987). Indeed, "presented" and "adhered" are not inconsistent. Rather, the difference in scope between independent claim 1 and independent claim 2 is that claim 2 contains the additional limitation that the dosage unit be "essentially water-free," while claim 1 requires that the dosage unit be a tablet. Therefore, Orexo's claim differentiation argument is not applicable. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (declining to apply the doctrine of claim differentiation where "there are numerous other differences varying the scope of the claimed subject matter," and noting that "overlapping patent claims are not unusual").

In any event, any presumption of claim differentiation would be rebutted by the clear teaching of the specification. "[T]he doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998). If the claims were construed as urged by Orexo, they would read on random mixtures, despite the patentees' admission that sublingual formulations of random mixtures were in the prior art. (*See supra* at 8-9, 15.)

Accordingly, Actavis' construction is correct, and the Court should find that "carrier particles" means "pre-formed particles comprising one or more pharmaceutically acceptable substances, attached to the surfaces of which are other particles"—as in an ordered mixture. [5]

[5] The proposed limitation that the carrier particles be "pre-formed" simply describes an inherent property of the carrier particle in an ordered mixture, and it is hardly disputable. Indeed, a microparticle cannot be presented on the surface of anything that has not yet been formed, and Orexo does not seriously contend otherwise. If this Court finds the "pre-formed" language confusing, Actavis submits that this side issue should not distract from the central point: the term "carrier particles," where other particles are present at their surface, signifies an ordered mixture that involves adhesion with other particles, and ***not*** a random mixture.

B. A POSA would understand the phrase "'presented' on the surface of 'carrier particles'" to signify adhesion as in an ordered mixture.

Term: "Presented at the exterior surfaces of the carrier particles"; "Presented upon the surface of carrier particles"

Orexo's Proposed Construction	Actavis' Proposed Construction
Positioned at the outside part or layer of the carrier particles	('996 patent) Admixed for a sufficiently long time to cover or affix to the outside part of layer of a pre-formed carrier particle ('330 patent) Affixed to the outside part or layer of carrier particles

As explained above, a POSA would have understood the term "carrier particles," as used in the claims, to signify the adhesion of an ordered mixture. (Berner Decl. at ¶¶ 32-36, 41-74.) That is because the complete phrase, explaining that microparticles are "presented upon the surface of carrier particles" indicates a special type of mixture involving the affixation of microparticles to a carrier—like an ordered mixture.[6] A POSA would understand that the word "presented" is used to answer the question: what is it that is affixed to the surface of the carrier particles? (Berner Decl. at ¶¶ 78, 86.) In other words, the claims make clear that it is the ***microparticles of buprenorphine*** that are attached to the carrier particles:

'996 patent, claim 1	'330 patent, claim 1
"wherein ***the microparticles of buprenorphine*** or a pharmaceutically-acceptable salt thereof are presented at the exterior surfaces of the carrier particles."	"***microparticles of a pharmacologically-effective amount of buprenorphine***, or a pharmaceutically-acceptable salt thereof, presented upon the surface of carrier particles . . ."

[6] Actavis agrees with Orexo that the "presented" phrase should be construed the same in both patents, despite the minor variation in wording. "Admix[ture] for a sufficiently long time," referred to in the proposed construction for the '996 patent, is simply another way of stating that the ***product*** is a mixture. If the Court finds this phrase confusing, it can be dropped from the construction without changing the meaning. The central point is that the "presented" phrase signifies a mixture that requires adhesion between particles, akin to an ordered mixture; the claims do not cover a random mixture.

The patentees chose to use the word "presented" to explain that the buprenorphine particles are the ones that are stuck to the carrier particles. A POSA would still understand the claim to exclude a random mixture. (Berner Decl. ¶¶ 76-90.)

Orexo argues that "presented" "does not address mixing, coverage, or affixation, but instead addresses location." (D.I. 72, Orexo's Op. Br. at 10; 19; D.I. 73, Peppas Decl. ¶ 50, 87.) That argument misses the point entirely, and does not make location inconsistent with affixation. For instance, a brick can be presented upon another brick with or without being adhered to the bottom brick. The same is true of ordinary particles. Thus, to say that a particle is "presented" on the surface of another particle says nothing about affixation. But to say that a particle is "presented" on the surface of a particular type of particle—a ***carrier particle***—absolutely signifies affixation. The placement of microparticles at the surface of "carrier particles" denotes an ordered mixture in which the microparticles ***are affixed*** to the carrier by the interactive forces that characterize such a mixture. (*See supra* at 2-7, 13-22; Berner Decl. at ¶¶ 41-74.)

And here, too, the alleged novelty of the asserted patents bears emphasis: if Orexo is permitted to construe affixation out of the claims, the claims will read on random mixtures, even though their alleged novelty lies in the sublingual administration of a composition characterized by intermolecular forces, as in an ***ordered*** mixture, not a random one. Put another way, a "carrier particle" with microparticles at its surface makes no sense in a random mixture because without any adhesive forces, the particles would all segregate from each other, and the product would fall apart. (Berner Decl. at ¶ 68, 76.)

All told, the claims' "presented" language is consistent with the POSA's understanding that the "carrier particles" of the claims must display the properties of an ordered mixture if other particles are at their surface. (Berner Decl. at ¶¶ 76, 78, 86.) Accordingly, the Court should

adopt Actavis' proposed construction of the entire phrase, "presented upon [or "at"] the surface of carrier particles" to mean "affixed" to the surface of "carrier particles."

II. In claim 1 of the '330 patent, the requirement that buprenorphine be "in contact with" citric acid but "not in the same particle" is further evidence that the claims of the '330 patent do not cover a random mixture.

Term: "wherein microparticles of buprenorphine or a pharmacologically-acceptable salt thereof are in contact with particles comprising citric acid, wherein the buprenorphine or pharmaceutically acceptable salt thereof and the citric acid are not in the same particle."

Orexo's Proposed Construction	Actavis' Proposed Construction
"In contact with" means touching at least in part, including the presence of quickly dissolving coatings on one or other, or both, sets of particles. "Not in the same" means in different. "Particle" means small piece or fraction.	Indefinite (assuming that Orexo's other proposed constructions are correct).

Claim 1 of the '330 patent further describes the orientation of the buprenorphine particles, and this additional limitation further shows that the claim describes an ordered mixture. Not only are the buprenorphine particles "presented upon the surface of carrier particles," they are also "in contact with" particles comprising citric acid—but "not in the same particle" as the particles comprising citric acid. Simply put: a POSA would understand this limitation as a requirement of an ordered mixture. (Berner Decl. at ¶ 92, 100.)

As the '330 patent explains, in an ordered mixture, "smaller particles . . . are attached to (i.e. adhered to or associated with) the surfaces of larger carrier particles." (JA25, '330 patent, col. 7 lines 5-19.) These mixtures are "characterized by interactive forces" between the carrier particle and the smaller particles attached to it, such as van der Waals forces, electrostatic or Coulomb forces, or hydrogen bonding. (*Id.*; *accord supra* at 2-7; Berner Decl. at ¶¶ 22-31) In

such a mixture, all microparticles are in contact with the surface of a carrier particle, and the microparticles are adhered to the surface of the carrier. (*Id.* at ¶¶ 93, 22-31.) But the microparticles and the carrier particles are still separate particles. (*Id.* at ¶ 93.)

Indeed, a POSA would understand that if the "carrier particles" have separate microparticles on their surface, the mixture ***must*** be characterized by adhesion. (*Id.* at ¶¶ 22-36, 41, 92,) That is because the term "carrier particles" that carry microparticles of drug can only be understood in two ways: a particle that carries a microparticle on its surface (akin to an ordered mixture), or a particle that carries a microparticle embedded within it (as in a random mixture, not an ordered mixture). (*Id.* at ¶ 32.) Thus, the term makes it even clearer that the claims do not cover random mixtures.

If, as Orexo contends, claim 1 is directed to a random mixture of citric acid and buprenorphine, then a POSA would not be able to understand the scope of the claim term with reasonable certainty. (*Id.* at ¶ 94.) How many buprenorphine particles are in contact with the citric acid particles before the mixture is deemed to infringe? All of them? Half of them? Twenty-two percent of them? Of the particles that are in contact, how much do they touch? Completely? Only in the slimmest of ways? As Dr. Berner explains, a POSA would have no way to know. (*Id.* at ¶¶ 97-98.) That is because a random mixture is just that—random. It can vary from no touching at all between certain particles to extensive touching, all depending on how well the product has been mixed, what ***else*** is in the mixture, and the order in which everything has been added. (*Id.* at ¶ 98.) Thus, a POSA would be bereft of guidance from the specification or file history as to the point at which such a random mixture becomes an infringing one, and the claim would therefore be indefinite. "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to

inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc*. 134 S. Ct. 2120, 2124 (2014). That would be the exact problem here if the claim were read to encompass a random mixture.

In sum, this claim term has a well-understood meaning as long as the claims exclude a random mixture. However, if the Court adopts Orexo's constructions that permit the claims to read on a random mixture sublingual tablet, the claim term would be indefinite as failing to provide the POSA with "reasonably certainty" as to the claim's scope.

III. A "pharmacologically-effective amount" or "effective amount" must elicit a therapeutic response.

Term: "Effective amount" / "Pharmacologically-effective amount"

Orexo's Proposed Construction	Actavis' Proposed Construction
An amount that elicits a (i.e., is capable of conferring a desired) therapeutic response or effect	An amount that elicits a therapeutic response

At the time of the March 6 exchange of proposed terms and constructions for the '996 patent, and again at the time of the May 20 exchange for the '330 patent, Actavis did not believe this term needed to be construed. (D.I. 72, Orexo's Op. Br. at 12, 21.) But Orexo had a different idea, and proposed that the "effective amount" be "capable of conferring" a therapeutic response. (*See id.*) Orexo proposed this construction—and insists on it now—in spite of the fact that the New Jersey court in *Mylan* construed "effective amount" in exactly the manner proposed by Actavis. (JA3215-16.) While Actavis was simply willing to adopt the *Mylan* court's earlier construction (which was originally proposed by Orexo), Orexo now unexplainably insists on changing course.

Orexo relies on a portion of the '330 specification that purports to define "pharmacologically effective amount." (D.I. 72, Orexo's Op. Br. at 12, 21.) This language—which Orexo failed to identify during the meet-and-confer process—is unremarkable: a "pharmacologically effective amount" must be "capable of conferring a desired therapeutic effect" ***depending on how the drug is administered***. The specification states that "pharmacologically effective amounts of naloxone . . . must be sufficient so as not to compete with the . . . buprenorphine . . . upon transmucosal administration, but to antagonize the effect of the buprenorphine . . . if an attempt is made by an opioid-addicted individual to inject a composition of the invention." (JA26, '330 patent, col. 9, lines 42-50.) For reasons that are not clear, Orexo seeks to only incorporate part of this definition into the claim.

Actavis simply proposes that this Court adopt the construction that has already been adopted by the *Mylan* court, and which Orexo itself proposed.

CONCLUSION

For the foregoing reasons, this Court should construe the disputed terms as proposed by Actavis so that the claims do not read on random mixtures.

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Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (Bar No. 110)
David A. Bilson (Bar No. 4986)
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806
Tel: 302.655.4200
Fax: 302.655.4210
jcp@pgslaw.com
dab@pgslaw.com

Of Counsel:
George C. Lombardi
Michael K. Nutter

Ivan M. Poullaos
Karl A. Leonard
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tel: (312) 558-5600
Fax: (312) 558-5700

Attorneys for Defendant Actavis Elizabeth LLC